**PHP59**

### TRENDS IN COMPARATIVE EFFECTIVENESS OF TOP 20 HIGHEST SELLING DRUGS

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**OBJECTIVES:** The recently made coverage decisions by UK's NICE, Scotland's SMC and the allocation of $1.1 Billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~$160B worldwide sales) **METHODS:** Drugs were categorized as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. Cost effectiveness Ratios (CERs) published in peer-reviewed journals and technology assessments conducted by payers were used for this analysis. **RESULTS:** There is a large variability in CERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. For example, CERs for clopidogrel range from $13,000 to $32,000, whereas for bevacizumab, it ranged from $125,000 to $350,000. Most striking was the CER for epotein alpha, which was ~$55,000 for Hb target levels of 11.0–12.0 g, but increased dramatically to $613,015 for target Hb of 12.0–12.5 g. Our analysis of 'generic alternatives' and the 'new clinical evidence' shows that previously deemed cost effective drugs could be re-assessed as being not cost effective when generics or new branded drugs with comparable efficacy become available (e.g. CATIE trial data for quetiapine). This would play a major role in the future, as more payers, including the US public payer CMS, explore ways to design a continuum in the coverage decision making process; implying that updated cost effectiveness ratios could change previously established coverage policies. **CONCLUSIONS:** This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

**PHP60**

### PRICING AND REIMBURSEMENT (P&R) IN BRIC COUNTRIES

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**OBJECTIVES:** To review the procedure and requirements for P&R of pharmaceuticals in Brazil, Russia, India and China. **METHODS:** A review was conducted of the official websites of governmental and public health institutions in the countries of interest. This review was complemented by interviews with key stakeholders in the respective countries. **RESULTS:** Free pricing of pharmaceuticals exist in general terms in Russia and India. In India, free pricing applies to non-scheduled drugs and pricing restrictions may be extended to drugs on the National Essential Medicines List. In China, prices are fixed by central government; whereas in Brazil external drug pricing is used as the major cost-containment measure. In Brazil, hospital drugs are reimbursed if they are on the Essential Medicines List and expensive therapies for cancer and chronic diseases are provided by the Exceptional Medicines Program. Reimbursement of retail drugs is limited to the Popular Pharmacy Program and the majority of costs are covered out of pocket. Similarly, the most drugs costs are covered out of pocket in India; with only established generics being reimbursed. Russia saw the federal reimbursement system, DLO, being introduced in 2005 to provide pensioners, invalids, and patients suffering from chronic diseases access to new therapies. In 2008 the DLO program was split into two subprograms: the expensive medicines program covering seven indications, with the remaining drugs on the DLO list being supplied through the ONLS program. In China, innovative drugs are currently negotiated at local level. **CONCLUSIONS:** Although cost-containment measures seen with more traditional markets are prevalent in the emerging markets, these markets are still undergoing significant changes in their P&R frameworks. Thus, as these markets develop their processes further, it will be necessary not only to consider P&R in the context of conventional wisdoms but also the political, social and cultural norms underpinning these systems.

**PHP61**

### POSITIVE DRUG LIST IN BULGARIA—5 YEARS LATER

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**OBJECTIVES:** To compare the regulatory framework and the structure of the Positive Drug Lists (PDL) in Bulgaria issued in 2003 and 2009. **METHODS:** Comparative legislation analysis was applied towards the requirements of the newly adopted regulation on PDL in 2008 with the regulation in 2003. It was analysed the requirement to the applicants, including the pharmacoeconomic evidences, selection procedure and the structure of the PDL. **RESULTS:** Main changes in PDL regulation are the following. In 2003 PDL the medicines were selected according to their innovativeness in one list under INN. In 2008 PDL medicines were separated in 4 lists according to the financing sources—Health Insurance, Hospital, Governmental budget and National Health programs. The criteria for the medicines evaluation were increased (efficacy, effectiveness, safety and pharmacoeconomic) and detailed in the new regulation. The PDL Committee is deciding both reimbursement status and level. The reimbursement level is defined on the basis of the international comparison with reimbursement levels in 7 reference countries calculated as lowest cost per DDD per unit. The changes in the structure of the PDL are the following. In 2003 there were list A with 625 INNs and list B with trade names that were updated on a yearly basis. In 2009 the four separated lists include 575 INNs presented with their trade names and dosage forms together. Reimbursement list 1 include 289 INNs, list 2 (518 INNs), list 3 (101 INNs) and list 4–59 INNs. Lots of INNs in all lists are overlapping. Also near 50 combinations are presented in the PDL. **CONCLUSIONS:** The new PDL includes less INNs as a total number and lots are overlapping between the lists. No National pharmacoeconomic guideline exists both for the PDL committee and manufacturers and thus no evidences for the influence of pharmacoeconomics exist.

## HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

**PHP62**

### FREE BUT VALUABLE: THE ECONOMIC SIGNIFICANCE OF SERVICES PROVIDED BY PORTUGUESE PHARMACIES

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**OBJECTIVES:** Besides dispensing medicines, pharmacies render other services including advice on health problems and on the best use of medicines; detecting problems in patients' medications; counseling on nutrition, etc. The majority of these services is free. Up to now, the volume of these services in Portugal were unknown. This paper presents 2008 estimates for the volume of pharmacy interventions and their economic value. **METHODS:** The data came from two 2008 surveys. A pharmacy survey was designed to estimate the volume and cost of the free interventions in community pharmacies in Portugal. In a general population survey, respondents answered a set of questions (choice experiments) designed to elicit their willingness to pay for a few typical services provided for free at community pharmacies. **RESULTS:** We estimate a total of 38.8 million free pharmacy interventions in 2008, 3.7 interventions per inhabitant. The top three pharmacy interventions were advice on non-prescription medicines, advice on prescription-only medicines and counseling related to point-of-care measurements and monitoring (cholesterol, pregnancy, etc.) and they used 2.8 million hours of work, about 13% of the total hours of work, at a cost of €54 million. This cost was equivalent to 20% of the pharmacies' gross income. We estimated the willingness to pay for the three main pharmacy interventions by conjoint analysis. The aggregate value of the services provided was estimated at €76.5 million. The net value, from society's perspective, for the three interventions was estimated to be €51 million. **CONCLUSIONS:** We found the volume of services provided at no charge to be significant, as were the resulting pharmacies' costs. The benefits to consumers were even larger generating a substantial net benefit to society.

**PHP63**

### CONSENSUS OF KEY DECISION MAKERS AND EXPERTS ON THE PRESENT AND FUTURE ON THE ASSESSMENT OF HEALTH TECHNOLOGIES IN SPAIN

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**OBJECTIVES:** Mechanisms for assessing health technologies (HT) have gone through major regulatory changes over the last five years in Spain. This study aims to determine the consensus level amongst decision makers and experts on the present and future of health technologies' assessment. **METHODS:** This is the second part of a two-phase study. A sample of participants and experts in HT evaluation was invited to participate on a two-round Delphi consultation (phase 2) about the most relevant and controversial issues identified in phase I. The present situation as well as desirable (D) and feasible (P) feature scenarios were considered. Consensus was reached when given statements were scored 7.5 or higher by 75% or more of the participants. **RESULTS:** Decision makers (n = 16) and experts (n = 8) participated in the study (mean involvement length in HT assessment: 12.4 [SD: 7.7] years). Present: Consensus was reached on that 1) the absence of established mechanisms to set priorities and define needs (83.3%), and the scarce political support (79.2%) explain the little influence of current legislation on HT implementation; 2) safety and efficacy (79.2%) are always considered to decide the implementation of HT. Coincidence of opinions existed for the poor definition of decision makers' roles and responsibilities (70.8%) and the deficient management of information between evaluation entities and decision makers (62.5%). Future: 1) Importance of value dossier and impact budget estimates (D: 95.8%, P: 12.5%) to support implementation; 2) efficiency and cost-effectiveness data will determine decisions (D: 91.7%; P: 12.5); 3) benefits for patients (D: 87.5%; P: 41.7%) and equity improvements (D: 91.7%; P: 16.7%) will be prioritised; 4) gains on patients' satisfaction, preferences and health related quality of life (HRQL) will deserve special attention (D: 75%; P: 12.5%) **CONCLUSIONS:** An important gap exists between desirable (D) and feasible (P) future scenarios. Agreement upon implementation mechanisms is mandatory. Patient centred results become relevant.

**PHP64**

### QUALITY ADJUSTED LIFE YEARS (QALYS) IN ECONOMIC EVALUATIONS OF HEALTH TECHNOLOGIES IN SPAIN: A REVIEW OF THE 2003–2009 LITERATURE

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**OBJECTIVES:** To appraise economic evaluations of health technologies that included QALYs as an outcome measure conducted over the last seven years in Spain. **METHODS:** Economic evaluations that included QALYs as an outcome measure,